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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,524	12/29/2003	Richard E. Parizek	1 1995.184 US D1	8568

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AKZO NOBEL PHARMA PATENT DEPARTMENT
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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,524	PARIZEK ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11,15,17-19,22-26,28-31,33,40,42,46 and 47* is/are pending in the application.

4a) Of the above claim(s) *41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,15,17-19,22-26,28-31,33,40,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9, 11,15,17-19,22-26,28-31,33,40,42, 46 and 47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, II and IV in the reply filed on February 24, 2005 is acknowledged. Therefore, claims 1-9, 11, 15, 17-19, 22-26, 28-31, 33, 40,42-4 and 46-47 have been rejoined. However claim 41 is part of non-elected group III and will not be rejoined. Therefore the requirement is still deemed proper and is therefore made FINAL.

Amendment Entry

2. The amendment filed February 24, 2005 has been entered. Claims 2 and 23 have been amended. Claims 10, 12-14, 16, 20-21, 27, 32, 34-39 and 43-45 have been cancelled. Claim 41 has been withdrawn. Claims 1-9, 11, 15, 17-19, 22-26, 28-31, 33, 40,42, and 46-47 are under consideration in this office action.

Priority

3. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all parent applications referenced should be included.

Specification

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

5. The use of the trademark QUIL A™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3, 5, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Acronyms like *C. chauvoei*, *C. septicum, C. novyi, C. sordellii* and *C. perfringens* Types C and D, and *H. sommus* must be spelled out when used for the first time in a chain of claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-8,11, 15, 17-19, 22-26, 28-30, 33, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts (WO 94/22476). The claims are drawn to a multicomponent vaccine for ruminants comprising an immunologically effective combination of a protective antigen component from at least six or seven clostridial organisms, a protective antigen from at least one non-clostridial organism, and an adjuvant wherein the dose is 3ml or less. The dependant claims are drawn to specific clostridial species, specific adjuvants and specific non-clostridial organisms.

Roberts (WO 94/22476) teach multicomponents clostridial vaccines using saponin adjuvants. Clostridial vaccines require adjuvants in order to increase potency and enhance stability (page 1 lines 32-35). In particular aluminum compounds are capable of adsorbing and precipitating clostridial toxoids as well as retaining toxoids at the injection site (page 1 lines 35-40). Other potent adjuvants used with clostridial vaccines include water-in-oil emulsion and carbopol polymers (page 2 lines 1-5). The author teaches a multicomponent clostridial vaccine comprising clostridial bacterins or toxoids derived from each of *Clostridium chauvoei, Clostridium septicum, Clostridium novyi, Clostridium sordellii, Clostridium perfringens,* Type C and Type D and a saponin adjuvant (page 2 lines 30-35). The authors teaches another multicomponent clostridial

vaccine comprising *Clostridium chauvoei*, *Clostridium septicum, Clostridium novyi, Clostridium sordellii, Clostridium perfringens,* Type C and Type D and *Clostridium haemolyticum,* and a saponin adjuvant (page 3 lines 1-5). Non-clostridial antigens may also be added to the vaccines to afford protection against a wide spectrum of diseases (page 5 lines 10-12). For example, antigens derived from *Moraxella bovis, Haemophilus somnus, Pasteurella hemolytica,* various respiratory viruses, as well as others, can be added to the multicomponent clostridial vaccine composition (page 5 lines 10-15). Therefore, the art meets the claim limitations drawn to a vaccine compositions comprising at least six or seven clostridial organisms, a protective antigen from non-clostridial bacterial organisms *Moraxella bovis and/or Haemophilus somnus*. Since the art teaches that vaccine may comprises antigens derived from various respiratory viruses, this encompasses bovine respiratory syncytial virus, thereby meeting the limitations instantly claimed. To immunize a bovine, the vaccine compositions are generally administered parenterally generally between 0.5ml to 10ml, more preferable 1 to 5ml (page 8 lines 24-34). Thus, the art teaches administering the vaccine at a low dose within the range of about 3ml or less, thereby meeting the claimed limitation. Example 1 teaches the preparation of an 8-way multicomponent clostridial vaccine including a saponin adjuvant.

Thus, Roberts teach a multicomponent vaccine for ruminants comprising an immunologically effective combination of a protective antigen component from at least six or seven specifically recited clostridial organisms, a protective antigen from at least

one non-clostridial gram-negative *M. bovis and/or H. somnus* or viral organism, and the specifically recited adjuvant wherein the dose is 3ml or less.

8. Claims 46-47 are rejected under 35 U.S.C. 102(a) as being anticipated by Roberts (WO 94/22476). Claims 46-47 are drawn to a method of immunizing an animal comprising administering an effective amount of the vaccine in claims 1 or 2.

Roberts (WO 94/22476) teach the vaccine composition of claims 1 and 2 at the low dose volume, see above. Moreover, Roberts teach other embodiments of the inventions are directed to methods comprising administering effective amounts of the subject vaccine composition to the bovine animal (page 3 lines 7-10). An effective amount of clostridial components will be that amount required to generate an amount of circulating antibody sufficient to prevent or reduce clostridial disease symptoms (page 7 lines 15-18). To immunize a bovine, the vaccine compositions are generally administered parenterally generally between 0.5ml to 10ml, more preferable 1 to 5ml (page 8 lines 24-34).

Thus Roberts teach a method of immunizing a bovine animal comprising administering an effective amount of the vaccine in claims 1 or 2, just as instantly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-6, 11, 15, 17-19, 28-29, 33 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Animal Pharm 203 p28 in view of Vision Vaccines. The claims are drawn to a multicomponent vaccine for ruminants comprising an immunologically effective combination of a protective antigen component from at least six or seven clostridial organisms, a protective antigen from at least one non-clostridial organism, and an adjuvant wherein the dose is 3ml or less. The dependant claims are drawn to specific clostridial species, specific adjuvants and specific non-clostridial organisms.

Animal Pharm 203 p28 teaches the approval for its Sommu Shield +7 way combination vaccine for cattle. The vaccine contains inactivated bacterin toxoid, which combines *Haemophilus sommus* with 7-way clostridial protection. The combination vaccine for cattle which combines six clostridial species, specifically *C. chauvoei, C. septicum, C. novyi, C. sordellii* and *C. perfringens* Types C and D, and a non-clostridial organism, *Haemophilus sommus.* However Animal Pharm does not specifically recite the use of an adjuvant or a dosage amount.

Vision Vaccines teaches an eight, seven and four way clostridial vaccine wherein the Vision 8 with Spur ™ comprises *C. chauvoei*, *C. septicum, C. novyi, C. sordellii, C. haemolyticum,* and *C. perfringens* Types C and D (page 5). The Spur adjuvant achieves the highest level of immunization and the lowest level of injection site defects (page 4). The dose for cattle is 2ml, because there is less tissue damage and the healing process is accelerated thus there is less likelihood of a blemished product (page 10). The Spur adjuvant has beneficial properties in terms of its suspension qualities; i.e., is does not settle out and can be used in lowers concentrations, unlike alum and aluminum hydroxide adjuvants (page 11).

Therefore, it would have been prima facie obvious at the time of applicants invention to modify the multicomponent vaccine for cattle comprising a non-reactive and immunologically effective combination of a protective antigen component from a plurality of clostridial organisms, a protective antigen component from a non-clostridial organism, *H. somnus* as taught by Animal Pharm., to further include adjuvant wherein the multicomponent vaccine is given at an administered dose of less then 3ml because Vision teach that the adjuvant has beneficial suspension qualities in a multicomponent vaccine composition containing clostridial bacterins when administered. One would have a reasonable expectation of success in incorporating the adjuvant and administering the vaccine at a low dose when the art already teaches that adjuvants can be used in clostridial vaccines; and may contain adjuvant : that has beneficial qualities when compared to other well-known adjuvants. Moreover, no more than routine skill is required to incorporate similar adjuvant that enhances the host's reaction, produces less

tissue damage and achieve immunization since the prior art clearly teaches the benefits of including adjuvants in multicomponent clostridial vaccine compositions.

10. Claims 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Animal Pharm 203 p28 in view of Vision Vaccines. Claims 46-47 are drawn to a method of immunizing an animal comprising administering an effective amount of the vaccine in claims 1 or 2.

Animal Pharm 203 p28 in view of Vision Vaccines have been discussed above as teaching the vaccine composition of claims 1 and 2 at the low dose volume. Moreover, Vision Vaccines teaches that the Spur adjuvant achieves the highest level of immunization and the lowest level of injection site defects (page 4). The dose for cattle is 2ml, thereby teaching administration at an effective amount. And it is administered either intramuscularly (IM) or subcutaneously (Sub-Q) to the cattle (page 11).

Thus Animal Pharm 203 p28 in view of Vision Vaccines teach are a method of immunizing a bovine animal comprising administering an effective amount of the vaccine in claims 1 or 2, just as instantly claimed.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 11, 15,17-19, 28-29, 33, 40 and 46-47 are rejected under the judicially created doctrine of double patenting over claims 3 and 7-9 of U. S. Patent No. 6,743,430 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The instant claims are drawn to a multicomponent vaccine for ruminants comprising an immunologically effective combination of a protective antigen component from at least six or seven clostridial organisms, a protective antigen from at least one non-clostridial organism, and an adjuvant wherein the dose is 3ml or less. The dependant claims are drawn to specific clostridial species, specific adjuvants and specific non-clostridial organisms.

US Patent 6,743,164 is drawn to a multicomponent vaccine for cattle, comprising an immunologically effective combination of a protective antigen component from at least 6 clostridial organisms, a protective antigen from a non-clostridial organism which is Haemophilus somnus, and further comprising an adjuvant wherein the vaccine is in a low doses volume of about 2.0ml or less. The dependant claims are drawn to the same six or seven species of clostridial organisms, the same specific adjuvants, and the same method of immunizing an animal.

Thus, the instantly claimed subject matter is fully disclosed in US Patent 6,743,430.

Prior Art

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stirling et al., (GB 2,030,043) teach inject able compositions for the treatment of helminthiasis a disease from parasitic worms that contain antigens prepared from the strains of Clostridia such as *Clostridium welchii (C. perfringens* types B, C, and D, *C. septicum, C. tetani,* C. *chauvoei, and C. novyi* in the presence of adjuvants such as carboxyvinyl polymers, aluminum hydroxide, aluminum phosphate or saponin.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
March 15, 2005

L. F. Smith
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